DEC 1 3 2013

4. Proposed Device Identification

Proposed Device Name: Endoscopic Linear Cutting Staplers with Single Use Loading Units
Device Common Name: Stapler

Regulatory Information:
Classification Name: Staple, Implantable;
Classification: II;
Product Code: GDW;
Regulation Number: 21 CFR 878.4750;
Review Panel: General & Plastic Surgery;

Intended Use Statement:
The Endoscopic Linear Cutting Staplers with Single Use Loading Units have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

5. Predicate Device Identification

510(k) Number:K120179
Product Name: Endoscopic Linear Cutting Staplers with Single Use Loading Units
Manufacturer: Reach Surgical, Inc.

6. Device Description

The proposed devices, Endoscopic Linear Cutting Staplers with Single Use Loading Units (SULU), are sterilized and disposable surgical instruments, which have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

It places four or six rows of titanium staples and simultaneously divides the tissue from central line. The Endoscopic Linear Cutter Staplers can be adapted for all of the SULU sizes available, and they may be reloaded and fired no more than 10 times in a single procedure.

The SULU has two configurations: (1) Straight SULU and (2) Articulating SULU, each of them has various specifications.

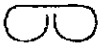
7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. These tests include: Physical Performance Testing, Endotoxin Testing, Package Integrity Testing, and Shelf Life Testing.

8. Substantially Equivalent (SE) Conclusion

The following table compares the proposed device to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table III-1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation Number	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The Endoscopic Linear Cutting Staplers with Single Use Loading Units have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.	Same
Cutting Mechanism	Linear	Same
Operation Principle	Manual	Same
Safety Mechanism	Green button for preventing from mis-firing.	Same
Suture Length	46, 61 mm	Similar
Closed Staples Height	0.75, 1.0, 1.5, 2.0 mm	Same
Closed Staples Form		Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Similar

The proposed device, Endoscopic Linear Cutting Staplers with Single Use Loading Units, is determined to be Substantially Equivalent (SE) to the predicate device, Endoscopic Linear Cutting Staplers with Single Use Loading Units (K120179), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Nanjing Maidixin Medical Device Company, LTD
% Ms. Diana Hong
Mid-Link Consulting Company LTD
P.O. Box 120-119
Shanghai, China 200120

December 13, 2013

Re: K130738
Trade/Device Name: Endoscopic Linear Cutting Staplers with Single Use Loading Units
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: November 7, 2013
Received: November 12, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II Indications for Use

510(k) Number: K130738

Device Name: Endoscopic Linear Cutting Staplers with Single Use Loading Units

Indications for Use:

The Endoscopic Linear Cutting Staplers with Single Use Loading Units have applications in general, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

☒PRESCRIPTION USE (Part 21 CFR 801 Subpart D) OR ☐OVER-THE-COUNTER USE (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130738